

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

PAMELA BUTLER, et al.,)	
)	
Plaintiffs,)	
v.)	No. 4:18-cv-01701-AGF
)	Lead Case
MALLINCKRODT, LLC, et al.,)	
)	
Defendants.)	

**DEFENDANT COTTER CORPORATION (N.S.L.)’S
MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION

Cotter Corporation (N.S.L.) (“Cotter”) should be granted summary judgment because—for three independent reasons—Plaintiffs cannot satisfy their burden to prove their public liability claims under the Price-Anderson Act (“PAA”), 42 U.S.C. § 2210, *et seq.*

First, Plaintiffs have no admissible evidence to show that Cotter ever breached the federal standard of care. As this Court has held, federal regulations at the time of Cotter’s conduct defined the levels of radiation that would protect members of the public from excessive exposure, and thus establish Cotter’s standard of care. Specifically, 10 C.F.R. § 20.105 set the permissible dose of radiation of 500 millirem per year that an individual could receive in an unrestricted area, and 10 C.F.R. § 20.106 defined the permissible concentrations of radioactive materials that could be released to an unrestricted area using a one-year average. But Plaintiffs have no admissible evidence showing that they were ever exposed to radiation in excess of this dose permitted by 10 C.F.R. § 20.105 or that Cotter ever released radioactive materials in excess of the levels permitted by 10 C.F.R. § 20.106.

Second, even if Plaintiffs’ claims could survive despite their failure to show exposure above the federal dose limit—as alleged in their complaints and as required by every circuit that has decided this issue—Plaintiffs have no admissible evidence to show that they were even exposed to any radiation released by Cotter above the natural background level. This Court has held, and Plaintiffs’ own evidence shows, that the natural background level of radiation is 360 millirem per year. But Plaintiffs have no proof of exposure above this level; in fact, their claimed exposures were far lower.

Third, Plaintiffs have no admissible evidence to prove specific causation. Under well-settled PAA, Eighth Circuit, and Missouri law, Plaintiffs have to carry their causation burden with expert testimony. And not only does Missouri law require expert testimony that radiation

caused or contributed to Plaintiffs' cancers, it also requires expert testimony to show that radiation exposure by Cotter alone was a substantial factor in causing the cancers. But Plaintiffs have no such testimony.

For each of these reasons, Cotter should be granted summary judgment.

II. LEGAL STANDARD

A. Summary Judgment Standard

Under Federal Rule of Civil Procedure 56(a), a court should grant summary judgment when “there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). On issues where the moving party does not have the burden of proof at trial, the moving party is required only to show that there is no evidence to support the non-moving party's claim. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The burden then shifts to the non-moving party to provide evidence sufficient to support a verdict in its favor. *Id.* If the non-moving party fails to satisfy its burden, the court should grant summary judgment on all or part of the claim. *Id.*; Fed. R. Civ. P. 56(a).

III. BACKGROUND

A. Factual Background

Starting in the 1940s, the U.S. government contracted with Mallinckrodt Chemical Works (whose successor-in-interest is Mallinckrodt LLC (“Mallinckrodt”)) to produce radioactive material for the Manhattan Project. Statement of Uncontroverted Material Facts (“SOF”) ¶ 37. As part of the Manhattan Project, Mallinckrodt processed uranium at a facility called the St. Louis Airport Site (“SLAPS”). *Id.* ¶¶ 37–39. Some of the radioactive material at SLAPS was then transported to an interim storage site in Hazelwood, Missouri, known as “Latty Avenue.” *Id.* ¶ 44. Between 1969 and 1973, Cotter possessed the radioactive material at Latty Avenue. *Id.* ¶ 45.

Plaintiffs Pamela Butler, Kenneth Koterba, Anthony Hines, and Emery Walick allege that they lived around Coldwater Creek at various points from the 1960s to 2014 and were thus exposed to radiation from Manhattan Project nuclear material in Coldwater Creek from the SLAPS and Latty Avenue sites. *Id.* ¶¶ 1–9. Butler developed breast cancer; Koterba developed a brainstem tumor; Hines developed mantle cell lymphoma; and Walick developed a medulloblastoma. *Id.*

B. Procedural History

Plaintiffs filed separate—albeit nearly identical—complaints against Mallinckrodt and Cotter on October 5, 2018. *Id.* ¶ 1. Each Plaintiff brought a public liability action under the PAA. *Id.* ¶ 1. This Court at first consolidated these actions into the lead case, *McClurg v. Mallinckrodt, Inc., et al.*, No. 4:12-cv-00361-AGF, under the Administrative Order Regarding Radionuclide Exposure Claims against Mallinckrodt LLC and/or Cotter Corporation (N.S.L.). *Id.* ¶¶ 10, 12. This Court later severed these actions from *McClurg* but kept them consolidated under the lead caption, *Butler, et al. v Mallinckrodt, Inc.*, No. 4:18-cv-01701-AGF. *Id.* ¶ 14.

After six years of litigation in *McClurg*, this Court recognized that “proof of causation will be a difficult burden for the Plaintiffs to meet.” *See* Case Management Order (“CMO”) No. 14, ECF No. 63-9. The Court thus entered CMO No. 14 and later applied the order to these cases. *Id.* As to Cotter, CMO No. 14 required Plaintiffs to produce expert reports that addressed, among other things, the concentrations of discharges at the boundary of the Latty Avenue site allegedly attributable to Cotter’s operations and whether the concentrations exceed the limitations in 10 C.F.R. 20.106, and specific causation for the injuries or illnesses alleged by the plaintiff from a medical expert opining to a reasonable degree of medical or scientific certainty that the plaintiff’s exposure to radiation from the Latty Avenue site attributable to Cotter’s operations at the site caused or contributed to the development of the injuries or

illnesses alleged by the plaintiff. CMO No. 14 at 9-10, ¶¶ a, b, c, e, ECF No. 63-9.

Plaintiffs produced expert reports under Federal Rule of Civil Procedure 26(a)(2) and the case management order. After years of expert discovery, on March 31, 2022, the Court ultimately granted Defendants' motions to exclude most of Plaintiffs' expert testimony. SOF ¶ 16. As to Cotter, the Court excluded: (1) the opinion of Plaintiffs' expert Dr. Wells that releases from Latty Avenue exceeded the federal standard of 10 C.F.R. § 20.106; (2) the entire testimony of Plaintiffs' expert Dr. Clark, who purported to calculate Plaintiffs' doses; and (3) the specific causation testimony of Plaintiffs' expert Dr. Hu. *Id.* ¶¶ 17–35.

IV. **ARGUMENT**

To prevail on a PAA claim, a plaintiff must establish that: (1) the defendant breached the levels permitted by the federal regulations in effect at the time (i.e., a breach of the federal standard of care); (2) the plaintiff was exposed to this radiation; (3) the plaintiff has injuries; and (4) radiation was the cause of plaintiff's injuries. *See In re TMI Litig.*, 67 F.3d 1103, 1119 (3d Cir. 1995), *cert. denied*, 516 U.S. 1154 (1996) (“*TMI IP*”); *In re TMI Litig.*, 193 F.3d 613, 659 (3d Cir. 1999) (“*TMI IIP*”) (agreeing with these elements); *McClurg v. MI Holdings, Inc.*, 933 F. Supp. 2d 1179, 1187 (E.D. Mo. 2013) (same); *McClurg v. Mallinckrodt, Inc.*, No. 4:12-CV-00361-AGF, 2017 WL 2929444, at *6 (E.D. Mo. July 7, 2017) (same). Because Plaintiffs cannot meet their burden to prove the first, second, or fourth element of their PAA claims, summary judgment is appropriate.

A. Plaintiffs Have No Admissible Evidence to Prove That Cotter Breached the Federal Standard of Care.

Cotter is entitled to summary judgment as a matter of law because the undisputed evidence does not show that Cotter ever breached the federal standard of care. As this Court observed when adopting the federal standard, “every Circuit Court that has [decided the issue], the Third, Sixth, Seventh, Ninth, Tenth, and Eleventh, ha[s] concluded that the maximum

permissible radiation dose levels set by federal safety standards establish the duty of care for radiation injuries.” *McClurg*, 933 F. Supp. 2d at 1187 (citations omitted). In other words, “[e]very federal circuit that has considered the appropriate standard of care under the PAA has concluded that [defendants] are not liable *unless they breach federally-imposed dose limits*.” *In re Hanford Nuclear Reservation Litig.*, 534 F.3d 986, 1003 (9th Cir. 2008) (emphasis added; collecting cases).

As to Cotter, Plaintiffs concede that “federal regulations governed levels of radiation and concentrations of radioactive material that could be created in unrestricted areas by licensees, without special authorization from the AEC.” Compl. ¶ 20, ECF No. 1. At the time of Cotter’s alleged conduct between 1969 and 1973, these federal regulations, contained in 20 C.F.R. § 20.105 and 20 C.F.R. § 20.106, explicitly defined the levels of radiation that would protect members of the public from excessive exposure. SOF ¶ 48. And these regulations remained unchanged during all relevant times. *Id.*

Section 20.105 permitted applicable releases of radiation so long as they were “not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of *0.5 rem [or 500 mrem]*.” *See* 20 C.F.R. § 20.105(a) (1960) (emphasis added); SOF ¶ 49. Section 20.106 also permitted releases of specific radioactive materials to unrestricted areas so long as their concentrations did not exceed specific limits set for each radionuclide using a one-year average. *See* 20 C.F.R. § 20.106 (1960); SOF ¶¶ 50 (providing table of permissible concentrations).

Plaintiffs cannot carry their burden to show that Cotter breached these federally imposed standards. And because this issue is beyond ordinary experience or knowledge, Plaintiffs had to satisfy their burden with expert testimony. *See McMunn v. Babcock & Wilcox Pwr. Gen. Grp., Inc.*, 869 F.3d 246, 267 (3d Cir. 2017) (expert testimony required under PAA); *Finestone v. Fla.*

Power & Light Co., 272 F. App'x 761, 768 (11th Cir. 2008) (same); *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010) (expert medical and exposure testimony “in a toxic tort case . . . is unquestionably required” under Missouri law); *Menz v. New Holland N. Am., Inc.*, 507 F.3d 1107, 1111 (8th Cir. 2007) (expert testimony is required under Missouri law “where the lay jury does not possess the experience or knowledge of the subject matter sufficient to enable them to reach an intelligent opinion without help” (brackets and quotations omitted)); *Pro Serv. Auto., LLC v. Lenan Corp.*, 469 F.3d 1210, 1214 (8th Cir. 2006) (same); *see also* CMO No. 14 (requiring expert testimony).

As to Section 20.105, Plaintiffs have no admissible evidence to show that they were ever exposed to radiation released by Cotter above 0.5 rem, or 500 mrem, in any calendar year; in fact, their claimed exposures were admittedly below this level. That failure of proof alone forecloses Plaintiffs' claims. *Finestone*, 272 F. App'x at 768 (“without their dose calculation experts, Appellants have not presented the sufficient admissible evidence of a breach of the Dose Limits needed to survive summary judgment on their Price-Anderson Act public liability actions”); *see also In re Hanford*, 534 F.3d at 1003; *McClurg*, 933 F. Supp. 2d at 1187. Moreover, allowing Plaintiffs' claims to proceed at levels below the federal standard would “put juries in charge of deciding the permissible levels of radiation exposure and, more generally, the adequacy of safety procedures at nuclear plants—issues that have explicitly been reserved to the federal government. This result would undermine the purpose of a comprehensive and exclusive federal scheme for nuclear incident liability.” *In re Hanford*, 534 F.3d at 1003 (internal quotations omitted).

As to Section 20.106, Plaintiffs tried to satisfy their burden with Dr. James Wells' expert testimony, but his opinions have been excluded. Dr. Wells sought to opine that Cotter breached Section 20.106 by releasing radon-220 and thorium-230 in excess of their relevant limits at the

boundary of Latty Avenue. Mem. and Order 30–31, ECF No. 104. But Dr. Wells’ opinion failed to satisfy Plaintiffs’ burden for three reasons. First, as this Court observed, Dr. Wells calculated thorium-230 releases based on quarterly, not annual, averages. *Id.* at 31. And it is undisputed that had Dr. Wells calculated Cotter’s thorium-230 releases based on annual averages, they would not have exceeded the limit. *Id.* Second, as this Court also observed, Dr. Wells calculated radon-220 releases for Latty Avenue based on the presence of the “K-65” residues *at SLAPS*, even though K-65 was never *at Latty Avenue*. *Id.* at 30. Third, Dr. Wells’ opinion was irrelevant to the duty owed to Plaintiffs because none of them claim exposure to excessive radiation released at the boundary of Latty Avenue. Based on Dr. Wells’ fundamental errors, the Court thus excluded his testimony that releases at Latty Avenue exceeded the federal limits in 10 C.F.R. § 20.106. *Id.*

Consequently, because Plaintiffs cannot produce any admissible evidence to satisfy their burden that Cotter ever breached the federal standard of care under the PAA, Cotter should be granted summary judgment.

B. Plaintiffs Have No Admissible Evidence to Prove Exposure to Excessive Radiation Released by Cotter Above the Normal Background Level.

Even if Plaintiffs’ claims could somehow survive despite failing to show exposure above the federal dose limit of 500 mrem per year (*Finestone*, 272 F. App’x at 768; *In re Hanford*, 534 F.3d at 1003; *McClurg*, 933 F. Supp. 2d at 1187; *see also* Pls.’ Compl. ¶ 12), summary judgment is still appropriate because Plaintiffs have no admissible evidence to show exposure to excessive radiation released by Cotter, much less exposure above the normal background level. *TMI III*, 193 F.3d at 659.

As *TMI III* explained, plaintiffs must show they were exposed to excessive radiation released by the defendant. *Id.* And because radiation is a “constituent element” of our environment and everyone is exposed to natural and man-made radiation, the exposure element

requires that plaintiffs prove they were exposed to excessive radiation released by the defendant “to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level.” *Id.* at 644, 659. As previously briefed and acknowledged by this Court in its *Daubert* ruling, “natural background” is a defined term in radiation science which, according to the Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry, and other authoritative legal and scientific sources, means an effective dose of 360 millirem per year. Mem. and Order at 35, ECF No. 104; *TMI III*, 193 F.3d at 659; *Hu Butler* 97:12–19; 95:25–97:19.

But Plaintiffs have no admissible evidence to show that they were exposed—let alone that their individual exposures exceeded the normal background level of 360 millirem per year—to excessive radiation released by Cotter. As noted above, because Plaintiffs had to satisfy this exposure element with expert testimony, *see McMunn*, 869 F.3d at 267; *Finestone*, 272 F. App’x at 768; *Junk*, 628 F.3d at 450; *Menz*, 507 F.3d at 1111; *Pro Serv. Auto*, 469 F.3d at 1214; *see also* CMO No. 14, Plaintiffs offered Dr. Clark’s testimony. In excluding Dr. Clark’s testimony, this Court made clear that his testimony was not sufficient reliable, and thus Plaintiffs are left with no expert evidence to prove the exposure element of their PAA claim. Mem. and Order at 33–37, ECF No. 104.

Plaintiffs therefore have no admissible evidence to prove any dose of radiation to which they were allegedly exposed in Coldwater Creek. And even if Plaintiffs could draw a general connection between their alleged exposures to radiation from Coldwater Creek, Plaintiffs have no admissible evidence to show any dose specifically tied to Cotter. Nor do Plaintiffs have any evidence that shows any dose exclusive of background radiation, which is naturally occurring and present everywhere. Consequently, even setting aside all the other shortcomings in Plaintiffs’ proof, they have no admissible way of proving how much, if any, radiation that they

were allegedly exposed to by Cotter, or differentiating any exposure allegedly attributed to Cotter from background radiation.

Moreover, even if this Court had allowed Dr. Clark's opinions to be presented to a jury, his opinions still could not have carried Plaintiffs' burden. As this Court explained, had Dr. Clark used the natural background number of 360 millirem per year, "he would have found that each Plaintiff's exposure was in fact lower than the background level." *Id.* at 35. And any possible exposure to radiation released by Cotter between 1969 and 1973 would be a mere fraction of each Plaintiff's total exposure. *See id.* at 2, 13–14. There is thus no question that Plaintiffs have failed to satisfy their burden to show exposure to excessive radiation released by Cotter. *TMI III*, 193 F.3d at 659.

C. Plaintiffs Have No Admissible Evidence to Prove Specific Causation.

Cotter should be granted summary judgment for a third, independent reason: Plaintiffs have no admissible evidence to prove specific causation, i.e., whether exposure to radiation actually caused each Plaintiff's cancer. Mem. and Order, ECF No. 104, at 21 n.7.

Under established PAA, Eighth Circuit, and Missouri law, Plaintiffs had to prove specific causation with expert testimony. *McMunn*, 869 F.3d at 267, 273; *Junk*, 628 F.3d at 450; *Golden v. CH2M Hill Hanford Grp., Inc.*, 528 F.3d 681, 683 (9th Cir. 2008) (affirming summary judgment in PAA case for lack of expert testimony showing specific causation). And not only does Missouri law require expert testimony to establish that radiation caused Plaintiffs' cancers, but it also requires expert testimony to prove that radiation exposure by Cotter alone was a substantial factor in causing the cancers. *See Chism v. W.R. Grace & Co.*, 158 F.3d 988, 991 (8th Cir. 1998) (citing *Hagen v. Celotex Corp.*, 816 S.W.2d 667, 669 (Mo. 1991)).

Indeed, as explained above, this Court specifically put Plaintiffs on notice to submit an expert report on "specific causation for the injury(ies) or illness(es) alleged by the plaintiff," in

which the expert “opin[ed] to a reasonable degree of medical or scientific certainty that the plaintiff’s exposure to radiation from the Latty Avenue site attributable to Cotter’s operations at the site caused or contributed to the development of the injury(ies) or illness(es) alleged by the plaintiff.” CMO No. 14 at 9–10, ¶ e, ECF No. 63-9.

But Plaintiffs have no such expert evidence. In its *Daubert* opinion, the Court excluded Dr. Hu’s specific causation opinion that “radiation caused or contributed to the Plaintiffs’ cancers.” Mem. and Order at 38–40, ECF No. 104. Thus, Plaintiffs cannot carry their PAA causation burden as a matter of law. *TMI II*, 67 F.3d at 1119; *Golden*, 528 F.3d at 683; *McMunn*, 869 F.3d at 267, 273; *Chism*, 158 F.3d at 991; *Junk*, 628 F.3d at 450.

Additionally, as with Drs. Clark and Wells, summary judgment would still be proper even if Dr. Hu’s opinion had not been excluded. Dr. Hu offered no testimony that radiation exposure released by Cotter—as opposed to natural or man-made radiation, Mallinckrodt, or any other source—was a substantial factor in causing Plaintiffs’ cancers. Just as in *Chism*, Plaintiffs therefore could not have established specific causation against Cotter. 158 F.3d at 991 (Missouri “standard requires evidence, in the form of expert testimony, ‘that the product of each defendant sought to be held liable was a ‘substantial factor’ in causing the harm’” (quoting *Hagen*, 816 S.W.2d at 670)).

Worse still, Dr. Hu’s causation theory was simply that any and every exposure to radiation—including even exposure below the natural background level—was “enough” radiation “to activate the disease.” See, e.g., Pls.’ Mem. 5, ECF No. 70. In other words, Dr. Hu claimed that any exposure *might* have caused Plaintiffs’ cancers based on the “scientific theory regarding radiation’s ability to cause cancer, known as the linear no-threshold model,” that “even very small doses of radiation can cause cancer.” *Id.* at 8; Hu Dep. 109:1–7, ECF No. 52-10 (“Q: Do you hold the belief to a reasonable degree of medical certainty that every exposure that is

above zero increases the risk of cancer? A: That is consistent with the linear no threshold model of carcinogenesis . . .”).

But Dr. Hu’s no-threshold theory does not, and cannot, prove whether any exposure from Cotter was actually a *substantial* factor in causing each Plaintiff’s cancer. *See Chism*, 158 F.3d at 991–92; *McMunn*, 869 F.3d at 273 (“demanding more than evidence of ‘any exposure’ makes it more burdensome . . . [b]ut the evidentiary regime that must apply in these cases necessarily requires that a jury find radiation was a substantial factor in causing a plaintiff’s injury”); *Nat’l Bank of Com. of El Dorado v. Assoc. Milk Producers, Inc.*, 191 F.3d 858, 861 (8th Cir. 1999) (linear-no-threshold theory “does not provide a scientific basis for a jury to find” causation); *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 677 (7th Cir. 2017) (“such a theory of liability would render the substantial-factor test essentially meaningless” (quoting *McIndoe v. Huntington Ingalls Inc.*, 817 F.3d 1170, 1177 (9th Cir. 2016))); *Reference Manual on Scientific Evidence* 643 (3d ed. 2011) (“even accepting the linear, no-threshold model for uranium mining and cancer, it is not enough to show exposure, you must show causation as well” (citation omitted)).

V. CONCLUSION

For these reasons, Cotter requests that this Court enter summary judgment against Plaintiffs and dismiss with prejudice the four *Butler* complaints against Cotter.

Dated: May 6, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 6, 2022, these papers were filed through the Eastern District of Missouri Court's CM/ECF system, which will automatically serve an electronic copy upon all counsel of record.

Dated: May 6, 2022

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